

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

Premier Medical Supplies, Inc., et al.,)	CASE NO. 1:07 CV 3809
)	
Plaintiffs,)	JUDGE PATRICIA A. GAUGHAN
)	
Vs.)	
)	
Michael O. Leavitt, Secretary of the Department of Health and Human Services, et al.,)	<u>Memorandum of Opinion and Order</u>
)	
Defendants.)	

INTRODUCTION

This matter is before the Court upon plaintiffs' Motion for Preliminary Injunction and Request for Hearing (Doc. 26). This case arises out of Medicare regulations governing the competitive bidding program for durable medical equipment and supplies. For the reasons that follow, the motion is DENIED.

FACTS

Plaintiffs, Premier Medical Supplies, Inc., Medic Home Health Care, LLC, Cornerstone

Carested, Inc. (collectively, "Plaintiff Suppliers"), Laszlo Nagy and Kit F. Shinkle (collectively, "Plaintiff Beneficiaries"), filed this lawsuit against defendants, Michael O. Leavitt, the Secretary of the United States Department of Health and Human Services ("Secretary"), and Kerry Weems, the Acting Administrator of the Centers for Medicare and Medicaid Services ("CMS").

Pursuant to Section 302 of the Medicare Prescription Drug, Improvement and Modernization Act ("MMA"), the Secretary implemented a competitive bidding program for the supply of certain durable medical equipment and supplies ("DMEPOS"). The Secretary began the implementation of the DMEPOS bidding process in ten selected metropolitan areas, including the Cleveland area, in 2007. The winning bidders were announced and the new program will be implemented on July 1, 2008.

On May 1, 2006, CMS published the proposed rules regarding the bidding process. The primary issue in the instant motion is whether CMS properly defined "small supplier." In the proposed rules, CMS indicates as follows,

[If you choose to comment on issues in this section, please include the caption "Opportunity for Participation by Small Suppliers" at the beginning of your comments.]

In developing bidding and contract award procedures, section 1847(b)(6)(D) of the Act requires us to take appropriate steps to ensure that small suppliers of items have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. Section 1847(b)(2)(A)(ii) of the Act also states that the needs of small suppliers must be taken into account when evaluating whether an entity meets applicable financial standards.

Size definitions for small businesses are, for some purposes, developed by the Small Business Administration (SBA) based on annual receipts or employees, using the North American Industry Classification System (NAICS). *Based on the advice from the SBA, we expect that most DME suppliers will fall into either NAICS Code 532291, Home Health Equipment Rental, or NAICS Code 446110, Pharmacies, since the SBA defines these small businesses as businesses having less than \$6 million in annual receipts.*

We propose using the SBA small business definition when evaluating whether a

DMEPOS supplier is a small supplier. We are relying on the expertise of the SBA to determine what constitutes the appropriate definition of a small supplier.

CMS allowed for a period of public comment.

(71 FR 25682)

Public commentators indicated their belief that “small supplier” should be defined to include only those suppliers with less than \$3 million in revenue. Specifically, CMS notes as follow,

Comment: Many commenters disagreed with using the definition of the SBA for a "small business" (less than \$6 million in annual receipts) because the CY 2003 Medicare data showed that at least 90 percent of suppliers had less than \$1 million in allowed charges. They recommended defining a small supplier as a supplier that generates less than \$3 million in annual receipts. The commenters believed that a lack of small supplier participation would negatively impact patient care. They added that small businesses would have to endure large expenses in order to participate in the Medicare DMEPOS Competitive Bidding Program.

Response: We agree with the commenters and, as we explained above, we have modified our definition of a small supplier so that it now means a supplier that generates gross revenue \$3.5 million or less in annual receipts.

In response, CMS revised the rule as follows,

The SBA definition refers to small businesses rather than “small suppliers.” We believe that \$6.5 million is not representative of small suppliers that provide DMEPOS items to Medicare beneficiaries, as it would encompass too many suppliers. In coordination with the SBA, we are defining a small supplier as a supplier that generates gross revenue of \$3.5 million or less in annual receipts and we are revising § 414.402 to include this definition.

Thus, in the final rule, “small suppliers” are those with revenues totaling less than \$3.5 million. In addition, the final rules limited the ability of suppliers to engage in “networking,” because of both the revised definition of “small supplier” and a prohibition on consolidation of billing services within a network.

Plaintiffs Medic, Cornerstone and Carested submitted bids under the final regulations.

Their bids were disqualified and non-winning. Plaintiffs allege that the bids were disqualified due to an alleged failure to provide financial information.¹

Thereafter, plaintiffs filed this lawsuit asserting seven claims for relief. Counts one and two allege equal protection and due process claims, respectively. Count three is a claim for violation of 5 U.S.C. 604(a)(5), the Regulatory Flexibility Act. Counts four and five allege violations of Sections 302 and 902 of the Medicare Modernization Act (“MMA”). Count six is a claim for violation of the Administrative Procedure Act (“APA”) and count seven alleges a claim for violation of procedural due process.

Plaintiffs move for a preliminary injunction halting the implementation of the DMEPOS competitive bidding scheme. Defendants oppose the motion.

STANDARD OF REVIEW

Federal Rule of Civil Procedure 65 governs the issuance of temporary restraining orders and preliminary injunctions.

“When considering a motion for a preliminary injunction, the district court should consider four factors: (1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury without the injunction; (3) whether issuance of the injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuance of the injunction.” *Rock and Roll Hall of Fame and Museum, Inc. v. Gentile Productions*, 134 F.3d 749, 753 (6th Cir. 1998). *See also Memphis Planned Parenthood, Inc. v. Sundquist*, 175 F.3d 456, 460 (6th Cir. 1999); *Schenck v. City of*

¹ It appears that the specific allegations regarding the reasons for the bid denial may have been inadvertently omitted from plaintiffs’ Second Amended Complaint. See, ECF 34-2 at ¶ 29).

Hudson, 114 F.3d 590, 593 (6th Cir. 1997); *J.L. Spoons, Inc. v. O'Connor*, 190 F.R.D. 433, 437-438 (N.D. Ohio 1999); *Crews v. Radio 1330, Inc.*, 435 F.Supp. 1002, 1005 (N.D. Ohio 1977).

A district court must make specific findings concerning each of these factors, unless analysis of fewer facts is dispositive of the issue. *Six Clinics Holding Corp., II v. Cafcomp Systems, Inc.*, 119 F.3d 393, 399 (6th Cir. 1997). However, not all the factors need be fully established for a temporary restraining order or injunction to be proper. *Michigan State AFL-CIO v. Miller*, 103 F.3d 1240, 1249 (6th Cir. 1997). None is a prerequisite to relief; rather, they should be balanced. *Connection Distributing Co. v. Reno*, 154 F.3d 281, 288 (6th Cir. 1998). While none of the factors are given controlling weight, a preliminary injunction should not be issued where there is no likelihood of success on the merits. *Michigan State AFL-CIO*, 103 F.3d at 1249. Where the court concludes that there is no likelihood of success on the merits, it need not address the other three factors. *Id.*

ANALYSIS

As grounds for their motion, plaintiffs argue that the Final Rule implemented by CMS violates the APA and the MMA because defendants did not comply with the public notice and comment requirements of those Acts. In addition, plaintiffs argue that the bid submission process was implemented in an arbitrary and capricious manner. Defendants dispute both arguments.

1. Jurisdiction

As an initial matter, the parties dispute whether this Court has jurisdiction to decide this

motion.²

In order to ascertain whether subject matter jurisdiction exists over plaintiffs' APA claim, the Court must determine whether or not any statute precludes judicial review. 5 U.S.C. § 701(a)(1). There is a "well-settled presumption favoring interpretations of statutes that allow judicial review of administrative action." *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 496 (1991). An act of Congress must provide "clear and convincing evidence" of an intent to preclude review. *Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967)

According to the government, Congress barred judicial review of the arguments raised by plaintiffs. Specifically, defendants point to 42 U.S.C. 1395w-3(b)(10), which provides as follows,

(10) No administrative or judicial review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of--

(A) the establishment of payment amounts under paragraph (5);

(B) the awarding of contracts under this section;

(C) the designation of competitive acquisition areas under subsection (a)(1)(A) of this section;

(D) the phased-in implementation under subsection (a)(1)(B) of this section;

(E) the selection of items and services for competitive acquisition under subsection (a)(2)

² Defendants filed a motion to dismiss this case. In addition, the parties dispute whether this Court has jurisdiction over the particular arguments presented in the motion for preliminary injunction. This Court's opinion regarding its jurisdiction is limited to the arguments raised in the motion for preliminary injunction. The Court will address the remaining jurisdictional arguments raised in the motion to dismiss at a later date.

of this section; or

(F) the bidding structure and number of contractors selected under this section.

Defendants argue that judicial review is not permitted regarding the APA claim asserted by plaintiffs Medic, Cornerstone and Carested. Defendants point out that this claim is premised on the allegation that defendants improperly refused to consider and/or accept bids from these suppliers. According to defendants, these claims involve the “awarding of contracts,” as well as the “bidding structure and number of contractors selected.” Because Congress expressly precluded judicial review of these types of claims, this Court lacks jurisdiction over this dispute.

In response, plaintiffs argue that their bids were not even considered, thus they cannot be challenging the “awarding of contracts.” Plaintiffs claim that they are challenging the “ability to be considered in the first place.”

Upon review, the Court concludes that it lacks jurisdiction over plaintiffs’ claims regarding the non-acceptance of their bids. In doing so, the Court rejects plaintiffs’ argument that Congress intended to preclude judicial review only with respect to contracts actually awarded by CMS. As an initial matter, this conclusion makes little practical sense, as suppliers receiving contract awards would be highly unlikely to seek judicial review. Moreover, the Court disagrees with plaintiffs’ suggestion that Congress precluded review for non-winning bids accepted by CMS, but intended to permit review of bids initially rejected by CMS. The entire bidding process is part and parcel of the “awarding of contracts,” for which judicial review is unavailable. Accordingly, the Court finds that it lacks jurisdiction over plaintiff’s APA claim to the extent it is based on CMS’s refusal to consider certain plaintiffs’ bids.

In addition, the parties dispute whether jurisdiction lies over plaintiffs’ claim that

defendants improperly enacted final regulations in violation of their obligations to engage in public comment and review. Defendants argue that this allegation relates to the awarding of contracts and the development of procedures related to the awarding of contracts. In support of their position, defendants point to 42 U.S.C. § 1395w-3(b)(6)(D), which provides as follows,

(b) Program requirements

(6) Participating contractors

(D) Protection of small suppliers

In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

According to defendants, plaintiffs' challenge essentially boils down to an argument that the alleged failure to engage in an appropriate public comment and review period regarding the definition of "small supplier" relates to the protection of small suppliers. Congress itself categorizes the "protection of small suppliers" as an activity related to the "development of procedures relating to bids and the awarding of contracts," which is outside the scope of judicial review under Section 1395-3(b)(10)(B) and (F).

Plaintiffs dispute that 42 U.S.C. §§ 1395(b)(10)(B) and (F) preclude judicial review. According to plaintiffs, they are not challenging the "bidding structure," but rather, the failure of defendants to properly comply with their obligations surrounding the creation of the regulations. Plaintiffs rely heavily on *Sharp Healthcare v. Leavitt*, 2008 U.S. Dist. LEXIS 28282 (S.D. Cal.

April 4, 2008) in support of their position. In *Sharp*³, the parties dispute the Secretary's enactment of a rule requiring some laboratories with face-to-face contact with beneficiaries to participate in the bidding process. The plaintiffs in *Sharp* argue that the rule directly contradicts express statutory language excepting all laboratories with face-to-face contact from participation in the bidding process. The Secretary argued that the dispute is not subject to judicial review because it relates to the "bidding structure," which is exempt under 42 U.S.C. § 1395-3(b)(10)(F). The court concluded that, contrary to the Secretary's position, Section 1395-3(b)(10)(F) does not foreclose judicial review. Specifically, the court reasoned that the provision precluding judicial review for disputes concerning the "bidding structure" is ambiguous. The court went on to conclude that the term "bidding structure" could reasonably be construed as "encompassing only the Secretary's establishment of the procedures or process that bidders must follow." *Id.* at *8. The court bolstered its analysis by indicating that Congress expressly exempted entities with face-to-face contact from the bidding process. It would make little sense for Congress to enact such a provision, while at the same time affording the Secretary unfettered discretion to enact rules directly contrary to its mandate.

The government distinguishes *Sharp* on the grounds that it involves a rule enacted by the Secretary that directly contradicts an express statute. Unlike *Sharp*, there is no statutory provision within the MMA directly contradicting the Secretary's definition of "small supplier." The government points out that, in fact, Congress granted the Secretary discretion to define "small supplier" by directing him to "develop[] procedures relating to bids and the awarding of

³ *Sharp* is an ongoing matter. As such, the court only reached the jurisdictional issues necessary to resolve the pending preliminary injunction motion.

contracts...to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program....”

Upon review, the Court finds that judicial review over plaintiffs’ claims regarding the failure of defendants to afford a proper “notice and comment” period before publishing the final rules is not foreclosed by 28 U.S.C. §§ 1395-3(b)(10)(B) and (F). Plaintiffs are not challenging the ultimate definition arrived at by the Secretary. Rather, at its core, plaintiffs’ challenge relates to the procedures followed by the Secretary in enacting regulations. The Court concludes that whether the Secretary engaged in a proper notice and comment period in defining “small supplier,” regardless of what definition he ultimately determines is appropriate, does not constitute a challenge to the “bidding structure.” In other words, the jurisdictional bar found in 28 U.S.C. §§ 1395-3(b)(10)(B) and (F) does not operate to bar APA challenges based on the general rulemaking duties imposed under either 5 U.S.C. § 553 or 42 U.S.C. 1395hh(a)(2). Accordingly, the Court finds that judicial review is available for plaintiffs’ challenge.

Defendants argue that if judicial review is available, the Court nonetheless lacks jurisdiction over plaintiffs’ claims because plaintiffs have not exhausted their administrative remedies. According to defendants, administrative review is available for a beneficiary or supplier who believes a claim should have been paid by Medicare. Defendants claim that, in essence, plaintiffs are seeking an extension of the current DMEPOS repayment system. Defendants argue that denial of a claim is a prerequisite to administrative review. Thus, defendants argue that until plaintiffs submit claims and those claims are denied, administrative review is not even possible. In response, plaintiffs argue that their claim regarding the failure of the Secretary to engage in a proper comment period is wholly unrelated to the claims submission

process. Moreover, plaintiffs point out that non-winning bidders are precluded by statute from submitting claims to Medicare.

Upon review, the Court agrees with plaintiffs. The Court finds that plaintiffs' challenge is wholly independent of the medicare reimbursement process. As such, exhaustion of administrative remedies is not required because the challenge is not reviewable on an administrative basis.

2. Preliminary Injunction

Having concluded that this Court has jurisdiction over plaintiffs' claim regarding the alleged failure of the Secretary to afford a proper notice and comment period, the Court turns to whether plaintiffs are entitled to the preliminary injunction they seek.

A. Likelihood of success on the merits

Plaintiffs argue that they are entitled to a preliminary injunction until such time as the Secretary is able to comply with his rulemaking requirements surrounding the definition of "small supplier." Specifically, plaintiffs argue that the final definition of small supplier is not a "logical outgrowth" of the proposed definition. As such, the final definition should have been treated as a proposed definition and the Secretary was statutorily obligated to provide a further opportunity for public comment and review. Plaintiffs point to 42 U.S.C. §1395hh(a)(4), which provides,

If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

Defendants argue that the final definition is a "logical outgrowth" of the proposed

definition. According to defendants, the “logical outgrowth” test is satisfied “where commentators should have anticipated that [the agency] might issue the final rule it did.” *City of Portland v. E.P.A.*, 507 F.3d 706, 715 (D.C. Cir. 2007). Defendants claim that the Secretary specifically sought comments on the definition of “small supplier,” and thus commentators should have been on notice that the Secretary would be defining “small supplier” in the final rule. Defendants point out that the Secretary received numerous comments concerning how “small supplier” should be defined. According to defendants, the fact that plaintiffs were satisfied with the definition as proposed, and chose not to comment, does not affect the analysis.

“Longstanding precedent instructs that “[n]otice is sufficient ‘if it affords interested parties a reasonable opportunity to participate in the rulemaking process,’ and if the parties have not been ‘deprived of the opportunity to present relevant information by lack of notice that the issue was there.’ *American Radio Relay League, Inc. v. F.C.C.*, 524 F.3d 227 (D.C.C.A. 2008)(internal citations omitted).

Upon review, the Court finds that plaintiffs fail to establish a likelihood of success on the merits. The Court agrees with defendants that the definition in the final rule is a logical outgrowth of the proposed definition. It cannot be disputed that the Secretary’s purpose in enacting the rule was to define “small supplier.” He proposed a definition and sought comment on his proposed definition. Although he ultimately defined small supplier as an entity with a lower threshold revenue, everyone was on notice that the purpose of the rule was to define “small supplier.” Parties agreeing with his proposed definition were afforded an opportunity to comment on why the proposed definition was appropriate. Likewise, parties disagreeing with the definition were also free to comment. The fact that the Secretary ultimately chose a different

definition of “small supplier” does not alter the fact that plaintiffs were provided a reasonable opportunity to participate in the rulemaking process. Plaintiffs were on notice that the issue of “how to define small supplier” was before the Secretary and it was reasonably foreseeable that the Secretary might adopt a different definition.⁴ *See e.g., Long Island Care at Home, Ltd., v. Coke*, 127 S.Ct. 2339 (2007)(fact that Department of Labor proposed exempting employees from Fair Labor Standards Act, yet ultimately declined to issue exemption, satisfied logical outgrowth test). *See also, City of Portland*, 507 F.3d at 715 (final regulation allowing for only two water treatment methods and adding a requirement for treatment of a parasite was “logical outgrowth” of proposed regulation, which set forth three acceptable alternatives and required treatment of finished water for viruses only); *National Ass’n of Homebuilders v. Army Corps of Engineers*, 453 F.Supp.2d 116, 126 (D.D.C. 2006)(final rule, which set forth higher acreage limits than proposed rule, satisfied “logical outgrowth” test).

Plaintiffs also argue that the proposed regulations regarding the ability of certain entities to participate in networks differed from the final regulation. Specifically, plaintiffs argue that

⁴ Plaintiffs also argue that the Small Business Act (“SBA”) requires federal agencies to use its definition of “small business,” *i.e.*, a business with less than \$6.5 million in revenue, unless a period for notice and comment is provided. Defendants point out that plaintiffs do not state a claim for violation of the SBA. To the extent plaintiffs rely on the SBA as support for the proposition that the “logical outgrowth” test is not satisfied, the argument is rejected. As defendants point out, CMS indicated in the proposed rule that it had also considered special rules for small suppliers with fewer than 10 full time employees. The Court agrees with defendants that the statement put plaintiffs on notice that CMS was analyzing various methods for determining which rules to apply to what size business, both in terms of revenue and number of employees. As such, it was foreseeable that CMS might consider a definition other than that found in the SBA.

the Secretary limited network participation to small suppliers and prohibited small suppliers from consolidating billing functions within a network. According to plaintiffs, these changes are not logical outgrowths of the proposed rules.

As an initial matter, plaintiffs do not point out specific language at issue in the regulations. Although they generally argue that the final regulations differ from the proposed regulations because of the ability of entities to participate, they do not compare specific language between the proposed and final regulations. As many commentators recognized, the proposed rules regarding networking are very complex. Thus, the Court endeavored to analyze the particular provisions that appear to be at issue. The gist of the proposed regulation concerns the participation in networks. It appears that the Secretary received numerous and substantial comments regarding networks. Commentators discussed the participation of certain entities in networks, the limitation on the number of entities entitled to participate in networks, and the potential for antitrust violations. The Court concludes that the proposed regulations were sufficient to alert plaintiffs that the issue of who could ultimately participate in networks was before the Secretary.

For these reasons, the Court concludes that plaintiffs fail to establish a likelihood of success on the merits.

B. Irreparable harm

The Court further concludes that plaintiffs fail to establish irreparable harm. Notably, three of the four Plaintiff Suppliers expressly allege that they qualify as “small suppliers” under the Secretary’s final rule. The only supplier not expressly alleged to qualify as a “small supplier” is Carested. Carested, however, submitted a bid to participate as a DMEPOS supplier.

Its bid was rejected for improper documentation. The Court has already ruled that it lacks jurisdiction to resolve this dispute. The Plaintiff Suppliers base their entire analysis of irreparable harm on either the rejection of their bids or a generalized inability to participate in the DMEPOS program. Likewise, the Court is not persuaded that the Plaintiff Beneficiaries have established irreparable harm. Plaintiff Nagy avers that he is fearful he will not receive the level of service he currently receives from his supplier. As an initial matter, the harm alleged is purely speculative in that he may very well receive excellent service from a new supplier. More important, however, plaintiffs do not tie this harm to the claim at issue in this motion, *i.e.*, the alleged failure of defendants to comply with the notice and comment provisions of either the APA or the MMA. Accordingly, plaintiffs fail to establish irreparable harm.

Having concluded that plaintiffs fail to establish either likelihood of success on the merits or irreparable harm, the Court need not reach the remaining factors.

CONCLUSION

For the foregoing reasons, the Court DENIES plaintiffs' Motion for Preliminary Injunction and Request for Hearing.

IT IS SO ORDERED.

/s/ Patricia A. Gaughan
PATRICIA A. GAUGHAN
United States District Judge

Dated: 6/30/08